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Applicant Initiated Interview Request Form

Application No.: 10/624,915 First Named Applicant: Pflueger
Examiner: Ragonese, A. Art Unit: 3743 Status of Application: PENDING

Tentative Participants:
(1) A. Ragonese (2) Frank J. Uxa
(3) _____ (4) _____

Proposed Date of Interview: 3/17/2005 **Proposed Time:** 10:30 (AM/PM)

Type of Interview Requested:
(1) [ ] Telephonic (2) [x] Personal (3) [ ] Video Conference

Exhibit To Be Shown or Demonstrated: [x] YES [ ] NO
If yes, provide brief description: an embodiment of an appliance of the invention

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
...			- -	- -	

SEE ATTACHED SHEET

Brief Description of Arguments to be Presented:

An interview was conducted on the above-identified application on _____.
NOTE: This form should be completed by applicant and submitted to the examiner in advance of the interview (see MPEP § 713.01).
This application will not be delayed from issue because of applicant's failure to submit a written record of this interview. Therefore, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible.

Applicant/Applicant's Representative Signature

Examiner/SPE Signature

Frank J. Uxa
Typed/Printed Name of Applicant or Representative

25,612
Registration Number, if applicable

ISSUES TO BE DISCUSSED:

Serial No. 10/624,915
Pflueger
Examiner: A. Ragonese

Issues	Claims/Figs.
(1) 35 USC 102(b)	Attached proposed claims Figs. 7, 17, 26
(2) 35 USC 103(a)	Same as (1) above

Prior Art

(1) Conrad et al (of record)
Doshi (of record)
Fege German Pat # 19920114A1 (copy attached)

(2) Same as (1) above

Brief description of arguments to be Presented:

Prior art does not disclose, teach or suggest the apparatus of proposed claims.

D-3077
Serial No. 10/624,915
Examiner: A. Ragonese

X. An apparatus for treating at least one of sleep apnea and snoring in a human or an animal having an oropharyngeal region with lateral and posterior walls, the apparatus comprising:

an appliance sized and structured to be placed in or outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal and, when so placed in an oropharyngeal region, having at least two lateral elements vertically spaced apart from each other with at least one of the lateral elements extending across the posterior wall, the appliance, when so placed in an oropharyngeal region, being effective in treating at least one of sleep apnea and snoring.

X+1. The apparatus of claim X wherein the at least two lateral elements are coupled together.

X+2. The apparatus of claim X wherein the at least two lateral elements are portions of the same structure.

X+3. The apparatus of claim X wherein the appliance has a longitudinal dimension and a lateral dimension which is greater than the longitudinal dimension when the appliance is so placed in an oropharyngeal region.

X+4. The apparatus of X wherein the appliance is sized and structured so that at least one of the lateral elements extends across the entire posterior wall when the appliance is so placed in an oropharyngeal region.

X+5. The apparatus of claim X wherein the appliance is sized and structured so that the at least two lateral elements extend across the posterior wall and at least portions of both of the lateral walls when the appliance is so placed in an oropharyngeal region.

X+6. The apparatus of claim X wherein the appliance is sized and structured so that the at least two lateral elements are vertically spaced apart from each other by varying distances over the lateral dimension of the at least two lateral elements when the appliance is so placed in an oropharyngeal region..

X+7. The apparatus of claim X wherein the appliance has a constrained configuration for delivery into the oropharyngeal region, and an open configuration when the appliance is so placed in an oropharyngeal region.

X+8. The apparatus of claim X7 wherein the open configuration is a concave loop configuration.

X+9. The apparatus of claim X wherein the appliance is made of a biocompatible metal.

X+10. The apparatus of claim X wherein the appliance is made of an elastic spring memory material.

X+11. The apparatus of claim X wherein the appliance is made of nitinol.

X+12. The apparatus of claim X wherein the appliance has a generally C-shape when viewed from above.

FEDERAL REPUBLIC OF GERMANY
GERMAN PATENT OFFICE
PATENT NO. 199 20 114 A1
(Offenlegungsschrift)

Int. Cl.[7]:	A 61 F 2/20 A 61 F 2/08
Filing No.:	199 20 144.5
Filing Date:	May 3, 1999
Date Laid-Open to Public Inspection:	November 9, 2000

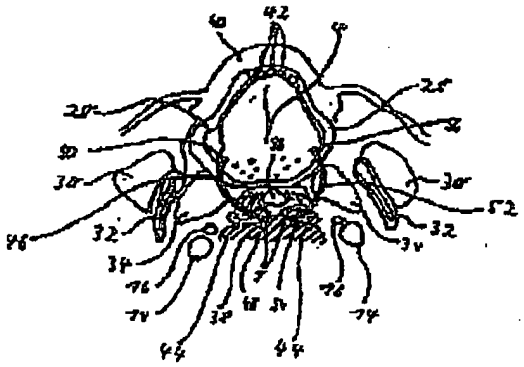
LATERAL PHARYNGEAL WALL IMPLANT

Inventor(s):	Application for not naming the inventor(s) has been filed
Applicant:	Dr. Wolfgang Fege, M.D. 33014 Bad Driburg, Germany
Agents:	Leine and Colleagues 30163 Hannover

The following statements are taken [unedited] from the documents submitted by the applicant.

[Abstract]

The subject matter of the present invention relates to a lateral pharyngeal wall implant, with a first and/or second implant (1; 1'), each of which comprises two implant elements (46,52; 60,61), each with an anterior end along the edge of the tongue and along the walls of the throat or along the edge of the velum of the soft palate (50,56; 72,74) and a posterior end along the cervical vertebra (48,54; 76,78). The two implant elements (46 to 52 and/or 60 and 61) of the implants (1,1') preferably have a curved shape so that, when implanted, the convex surface is facing the inner surface of the throat or the mucous membrane of the throat. The posterior end (48,54; 76,78) of the implanted implant elements is attached to the cervical vertebral column (38) and is supported by said column or by the tissue in front thereof or is implanted (attached) in the tissue in front thereof.



Description

The subject matter of the present invention relates to a lateral pharyngeal wall implant.

In the obstructive sleep apnea syndrome which, in conformity with the specialized literature, will hereinafter be referred to as OSAS, recurrent cessations of respiration occur in the slow-wave sleep phases and in the REM (Rapid Eye Movement) sleep phases, during which cessations of respiration the muscle of the tongue relaxes, which, due to gravity, causes especially the body of the tongue to fall back. In the extreme case, the body of the tongue comes to rest against the posterior wall of the throat and thereby blocks the air passage in this area. In addition, a collapse of the lateral walls of the throat can also contribute to the blockage of the respiratory passages.

The cessations of respiration that occur as a result thereof come to an end only when the oxygen saturation of the blood and the oxygen deficiency in the brain lead to a sudden arousal until a shallower sleep phase or complete awakening occurs, in the course of which the muscular tension again increases sufficiently for the body of the tongue to be retracted from the posterior wall of the throat and for the lateral walls of the throat to become tenser again and to open up the respiratory passages. Thereafter, sleep slowly drifts into an REM or deeper sleep phase until the cycle described above starts anew.

OSAS must be treated since the regularly recurring oxygen saturations of the blood during sleep can lead to injuries to the myocardium, to coronary diseases, to cerebrovascular diseases with a higher incidence of strokes, shrinkage of the brain and hypertensive crises, and to a large number of hormonal imbalances. Furthermore, the frequent absence of the slow-wave sleep phases, the interruption of the REM sleep phases and the frequent arousals lead to lack of drive, daytime sleepiness, and a tendency to suddenly fall asleep during the day, which can lead to accidents while operating machinery and driving automobiles.

It is known that OSAS can be treated during sleep with the use of an extracorporeal compressor for generating a continuous positive pressure in the nasopharyngeal space via a tube and a nose mask. In the long run, such a treatment with positive pressure can lead to an overdistention of the pulmonary alveoli and to a shortening of the alveolar septa, the so-called pulmonary emphysema, which in turn can lead to a decrease of the overall lung diffusion surface area and to respiratory distress. An additional disadvantage is that in the presence of excess pulmonary pressure, the pumping action of the right ventricle of the heart must increase so as to be able to push the same quantity of blood against the increased counterpressure in the lung. This can lead to right-sided myopathy. Yet another disadvantage is that having to wear a mask while sleeping is inconvenience and uncomfortable.

From the book by L. Grothe and H. Schneider, "Schlafapnoe- und kardiovaskuläre Erkrankungen" [Sleep apnea and cardiovascular diseases], Thieme 1996, it is known that it is possible to use oral prostheses which are inserted into the throat at bedtime and the purpose of which it is to push the base of the tongue forward. Such oral prostheses, however, promise success only if the OSAS is mild and, moreover, are tolerated only by a small percentage of patients due to complicated handling procedures and discomforts.

To treat OSAS, it is also known to use surgical treatment measures which aim mainly at improving the air flow in the nasal and nasopharyngeal area. An attempt has even been made to move forward the upper and lower jaw or a quadrilateral sawed out of the lower jaw bone with attached muscles of the tongue in the chin area and thus to improve the air flow. This is a major surgical intervention which places a considerable strain on the patient and which, furthermore, rarely leads to acceptable results since, like the surgical measures described earlier, such an intervention only indirectly treats the problem since it does not causally prevent the body of the tongue from falling back and from coming to rest against the posterior wall of the throat and thus from blocking the respiratory passage.

The unpublished German Patent Application with the official filing number 197 56 956 describes an implant for implantation in a tongue, on which implant an attachment element for attachment to the hyoid bone or on the tissue lateral to the tongue as well as a support element which extends from the attachment element into the area of the base of the tongue and substantially at right angles to the direction of the tongue are disposed.

The problem to be solved by the present invention is to make available a lateral pharyngeal wall implant which effectively prevents or reduces the OSAS and which largely eliminates potential problems the patient may suffer from, such as swallowing difficulties and disturbances during sleep, especially in cases in which the implant for implantation in the base of the tongue as described in the German Patent Application No. 196 56 956 does not suffice to treat the OSAS.

The problem underlying the present patent is solved by the teaching of Claim 1.

The central idea of this teaching is to make available a lateral pharyngeal wall implant which can be implanted so that one end of the implant is disposed along the cervical vertebra and the other end is disposed along the lateral edge of the tongue. The lateral pharyngeal wall implant can be advantageously used if the supporting effect of the implant for implantation in the base of the tongue discussed above does not suffice and a reinforcement of the implant for implantation in the base of the tongue or a replacement of the implant for implantation in the base of the tongue is not feasible for various reasons. A potential reason might be the risk of considerably impairing the mobility of the base of the tongue or the fact that the implant implanted in the base of the tongue has healed so well that any additional surgical manipulation in the area of the implant might lead to the formation of excessive scar tissue or to an impairment of the surgical result due to other causes. In this case, the lateral pharyngeal wall implant according to the present invention would mainly serve to support the edge of the tongue; a secondary effect would be to support the lateral tissue of the throat. The lateral pharyngeal wall implant according to the present invention can be advantageously used also in cases in which OSAS is suspected to be contributorily caused to a large extent by the collapse of the lateral walls of the throat.

In this case, the lateral pharyngeal wall implant would mainly serve to support the lateral tissue of the throat, and the secondary effect would be the support of the edge of the tongue. The lateral pharyngeal wall implant according to the present invention makes it possible to support the lateral edge of the tongue more effectively than the sole use of an implant for implantation in the base of the tongue, without the overall action of the supporting force being transmitted across the base of the tongue, thus ensuring that, in spite of the greater lateral tongue support action, said base of the tongue remains more mobile than if only the implant for implantation in the base of the tongue were to be used and the act of swallowing is less impaired since the action of the supporting force is better distributed over the entire cross section of the throat and/or over a portion of the longitudinal extension of the throat.

The implant elements of the implants are preferably designed so as to be curved so that in the implanted state, the convex surface is facing the inside wall of the throat and the mucous membrane of the throat. This ensures that an especially good supporting action is exerted on the lateral edge of the tongue and/or the lateral tissue of the throat.

Additional advantageous and useful embodiments of the solution of the problem according to the present invention follow from the dependent claims.

The present invention will be explained in greater detail on the basis of the attached drawing in which practical examples are illustrated.

As can be seen,

elements 46,52 of implant 1, they have a curved design so that, when implanted, the convex side is facing the inside of the throat and the mucous membrane of the throat. The use of implant 1', i.e., of implant elements 60 and 61, has advantages especially if the throat above the dorsum of the tongue, i.e., in the region of the palatopharyngeal and palatoglossal arches, collapses during sleep and therefore requires that this regions be supported. The anterior end 76,78 of implant elements 60,61 of implant 1' is attached to cervical vertebral column 38 or is supported by said vertebral column or it is attached to the tissue in front thereof or supported by said tissue. The anterior end 72,74 of implanted implant elements 60,61 is attached in the tissue located in the vicinity of the lateral posterior edge of the hard palate 6 and/or pterygoid bone 70 or is supported thereby.

Figure 3 shows the right implant element 52 of implant 1 according to the present invention and implant element 61 of implant 1' according to the present invention in the implanted position, with the right side of the face in the drawing having been removed and with the right side of the mouth and the right side of the nose being exposed for the sake of clarity.

Implant elements 46,52,60,61 are substantially designed in the form of bands, with bands being defined to also include a structure which, although flat, can vary as to thickness and width in certain areas along the way. The lengthwise dimension of the implant elements is preferably greater than the thickness of the implant, and the cross-sectional dimension can be variable. At least once implanted, the implant elements have a convexly curved shape to fit the lateral wall of the throat.

Implants 1 and 1' can be used separately or in combination with each other or separately or in combination with an implant for implantation in the base of the tongue, especially in cases in which the main causes of OSAS have been attributed to the fact that the tongue is falling back and that the lateral walls of the throat collapse. Which implants are chosen depends on which structures collapse during sleep.

The lateral pharyngeal wall implants according to the present invention are preferably designed to be extremely soft so as to avoid an irritation of or an injury to the important structures, such as nerves and vessels. The implants are made of cultured endogenous tissue or of a synthetic material or of a combination of both materials. Instead of cultured endogenous tissue, it is also possible to use endogenous tissue that has been harvested from another site.

Claims

1. A lateral pharyngeal wall implant, with a first and/or a second implant (1; 1'), each having two implant elements (46,52; 60,61), each implant element having an anterior end along the lateral edge of the tongue and along the lateral wall of the throat or the lateral edge of the

velum of the soft palate (50,56; 72,74) and a posterior end along the cervical vertebra (48,54; 76,78).

2. The lateral pharyngeal wall implant as claimed in Claim 1, characterized in that the two implant elements (46 and 52 and/or 60 and 61) of the implants (1,1') are designed to have a curved shape so that, when implanted, the convex surface is facing the inside surface of the throat or the mucous membrane of the throat.

3. The lateral pharyngeal wall implant as claimed in Claim 1 or 2, characterized in that the posterior end (48,54; 76,78) of the implanted implant elements (46,52; 60,61) is attached to the cervical vertebral column (38) or is supported by said vertebral column or by the tissue located in front thereof or is implanted (attached) in the tissue located in front of said column.

4. The lateral pharyngeal wall implant as claimed in Claim 1 or 2, characterized in that the anterior end (50,56) of the implanted implant elements (46,52) of the first implant (1) is located in the surrounding tissue along the side of the tongue or is supported by the lateral region of the tongue or is implanted (attached) in the lateral region of the tongue.

5. The lateral pharyngeal wall implant as claimed in Claim 1 or 2, characterized in that the anterior end (72,74) of the implanted implant elements (60,61') of the second implant (1') is supported by the tissue located in the environment of the lateral hard palate (6) and/or the pterygoid bone (70) or is implanted (attached) therein or is supported by or attached to the hard palate or pterygoid bone as such.

6. The lateral pharyngeal wall implant as claimed in any one of the preceding claims, characterized in that the implants (1,1') are implanted in part or as a whole.

7. The lateral pharyngeal wall implant as claimed in any one of the preceding claims, characterized in that the implants (1,1') are made of a synthetic material and/or cultured endogenous tissue and/or of an endogenous tissue harvested from a different site.

8. The lateral pharyngeal wall implant as claimed in any one of the preceding claims, characterized in that the implant elements (46,52; 60,61) of the implants (1,1') are bandlike structures.

9. The lateral pharyngeal wall implant as claimed in any one of Claims 1 through 7, characterized in that the implant elements (46,52; 60,61) of the implants (1,1') are structures, the lengthwise dimension of which is greater than the thickness of said structures and the cross-sectional dimension of which can vary both between two implants and within one implant.

10. The lateral pharyngeal wall implant as claimed in Claim 9, characterized in that in certain areas, the flat structure has a different thickness both in the lengthwise and/or in the cross-sectional direction.

Includes 3 pages of drawings

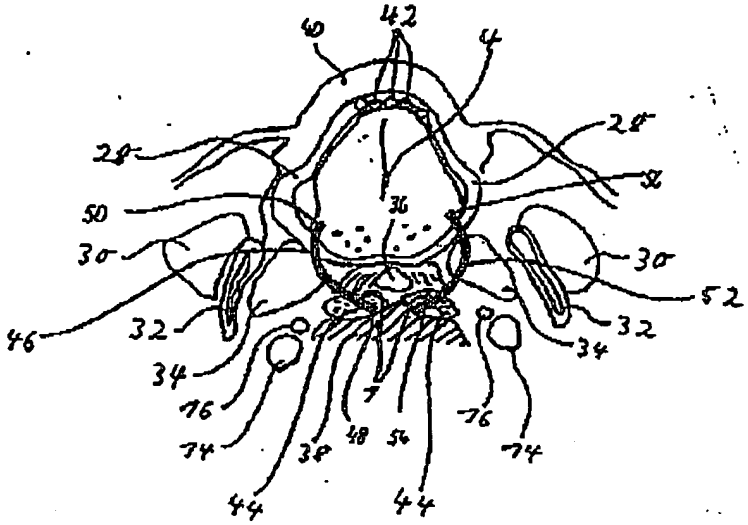


Figure 1

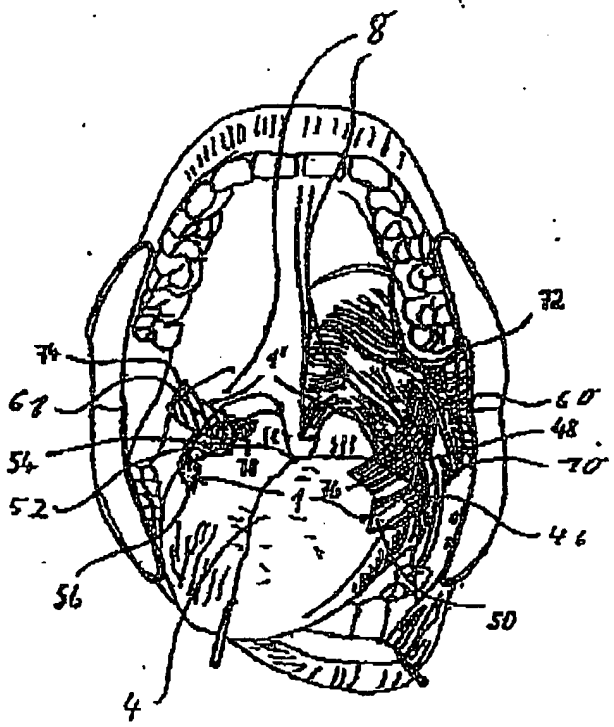


Figure 2

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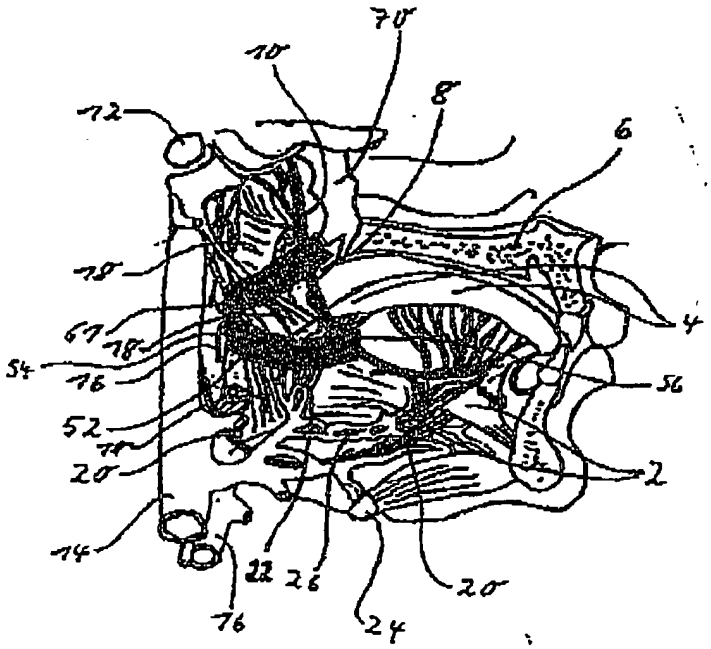

Figure 3